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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/767,859	01/28/2004	Kevin Stamp	7095MH-1	2989

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EXAMINER

GRAY, PHILLIP A

ART UNIT	PAPER NUMBER
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3767

DATE MAILED: 09/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/767,859	Applicant(s) STAMP, KEVIN	
	Examiner Phillip Gray	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 June 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 and 28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 and 28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>8/24/2006</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This office action is in response to applicant's communication of 6/22/06.

Currently claims 1-28 are pending and stand rejected.

Response to Arguments

Applicant's arguments filed 6/22/2006 have been fully considered but they are not persuasive. Applicant argues that the claim language "enabling a desired dose of medicament to be drawn into said nozzle, ready for injection" is not shown or taught in the prior art of record, namely Landau. It is examiner's position that Landau and the prior art of record, does anticipate and teach this claim limitation.

It is examiners position that the claim does not require that the dose be a variable selectable doseage but rather a "desired dose". During examination, claim limitations are to be given their broadest reasonable reading. Given the broadest reasonable reading of "enabling a desired dose of medicament to be drawn into said nozzle, ready for injection", Landau would not be precluded from anticipating this because a "desired dose" is drawn into the nozzle. It is not required by the claim language that the desired dose is variable, selectable or otherwise. As explained to applicant's representative in the previous interview, there is no directional or functional limitations included into the claim limitation of dose "drawn into said nozzle". In sum it is examiners position that the landau dose would be a desired dose by the user and this dose would be drawn into the nozzle ready for injection. It is recommended that the exact difference and

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improvement of the instant invention that applicant feels is not shown or taught by the prior art should be amended to the language of the claims.

Applicant further argues that since a desired dose isn't taught then the guiding and indication means are not shown and other depending claims are not shown either. It is examiners position that given the broadest reading for the claim limitation the desired dose is shown, see arguments above and below. But the Landau device does show helical guiding means with tabs, and indications of medicament dosage, see rejection below.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5-22, 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Landau (U.S. Patent Number 6,264,629). Landau patent discloses a gas-powered single-use needle-less hypodermic jet injection apparatus and method. Landau discloses an outer housing (62) having a nozzle (46a), an inner housing (12c) located within the outer housing, a piston and ram (50e, 60) to drive the medicament, a pierceable gas cylinder (82) to drive the piston and ram, and a guide means for axial movement of the inner housing with the nozzle and outer housing (see figures 1-3). Landau discloses a visible dosage scale indicator that is a flexible indexer tab (24), a

helical groove with pits and discrete tapered teeth (64), and vertical walled endstop for stopping indexer tab (24), and a fixed locking retainer sleeve with a plurality of retention elements to engage the gas cylinder (82) in two positions for engagement and prevent movement (184, see figures 7-8). Further, Landau discloses a gas cylinder pierceable by a piercing means (80) within the inner housing, forward biased by a spring (90), further with a seat intermediate the cylinder (84a), fixed inner member retainer sleeve (68).

Claims 1- 22,28 rejected under 35 U.S.C. 102(b) as being anticipated by Landau (U.S. Patent Application Number 2001/0004681). Landau patent discloses a gas-powered single-use needle-less hypodermic jet injection apparatus and method. Landau discloses an outer housing (62) having a nozzle (46a), an inner housing (12c) located within the outer housing, a piston and ram (50e, 60) to drive the medicament, a pierceable gas cylinder (82) to drive the piston and ram, and a guide means for axial movement of the inner housing with the nozzle and outer housing (see figures 1-3). Landau discloses a visible and audible dosage scale indicator (see paragraphs 82-85) that is a flexible indexer tab (24), a helical groove with pits and discrete tapered teeth (64), and vertical walled endstop for stopping indexer tab (24), and a fixed locking retainer sleeve with a plurality of radially spreading retention elements to engage the gas cylinder (82) in two positions for engagement and prevent movement (184, see figures 7-8). Further, Landau discloses a gas cylinder pierceable by a piercing means (80) within the inner housing, forward biased by a spring (90), further with a seat intermediate the cylinder (84a), fixed inner member retainer sleeve (68).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 17-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Landau '629 in view of Landau (U.S. Patent Application Number 2003/0093030). Landau '629 discloses the claimed invention except for the locking sleeve, fingered collet and button to control the cylinder movement. Landau '030 teaches that it is known to use the locking sleeve, fingered collet and button to control the cylinder movement, (as set forth in paragraphs from 18-32 and figures 1-4, 9-10), to prevent unwanted cylinder movement and provide a stable gas delivery. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the needle free injection device as taught by Landau '629 with the locking sleeve, fingered collet and button to control the cylinder movement as taught by Landau '030, since such a modification would provide the needle free injection device with the locking sleeve, fingered collet and button to control the cylinder movement prevent unwanted cylinder movement and provide a stable gas delivery.

Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Landau.

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Landau discloses the claimed invention except for an integrally formed ram and piston. It would have been obvious to one having ordinary skill in the art at the time the invention was made to integrally form the ram and piston, since it has been held that forming in one piece an article which has formerly been formed in two pieces and put together involves only routine skill in the art. *Howard v. Detroit Stove Works*, 150 U.S. 164 (1893).

Claims 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Landau '629 in view of Landau et al. (U.S. Patent Number 6,752,781). Landau '629 discloses the claimed invention except for the ram connected by frangible knuckle joints to the inner housing. Landau '781 teaches that it is known to use ram connected by frangible knuckle joints to the inner housing, as set forth in column 10 and line 17 to column 11 line 64 (also figure 9-11), to provide a greater control of the ram and a lost motion preventer mechanism. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the needle free injection device as taught by Landau '629 with ram connected by frangible knuckle joints to the inner housing as taught by Landau '781, since such a modification would provide the needle free injection device with ram connected by frangible knuckle joints to the inner housing for providing a greater control of the ram and a lost motion preventer mechanism.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gray whose telephone number is (571) 272-7180. The examiner can normally be reached on Monday through Friday, 8:30 a.m. to 4:30 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER

Kevin C. Sirmons